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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/367,950	08/18/1999	TOMMY EKSTROM	06275/188001	4952

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EXAMINER	
KIM, JENNIFER M	
ART UNIT	PAPER NUMBER
1617	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

Office Action Summary	Application No.	Applicant(s)	
	09/367,950	EKSTROM, TOMMY	
	Examiner	Art Unit	
	JENNIFER MYONG M. KIM	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *4/3/2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *13-36,38 and 42-53* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13-36,38 and 42-53* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/3/09;5/27/09;6/16/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 3, 2009 has been entered.

Response to Arguments

Applicants' arguments filed April 3, 2009 have been fully considered but they are not persuasive. **With regard to 35 U.S.C. 101 rejection**, Applicants argue that there is nothing in the statue nor the case law supporting the Examiner's assumption that only step of actually administering the combination to the patient could possibly qualify as a "reduction" or "transformation". The instant method claims transforms an asthma patient into someone provided with both (1) an inhaler and (2) a recommendation as to how to use the inhaler, and therefore, the method also qualifies as "practical" to the patient who thereafter understands how to utilized the provided inhaler. This is not found to be persuasive because the rejection was made based on the Board's remand August 28, 2007 (see page 10 of the remand). It is noted that the instant claim 13,

requires 1) “providing” an inhaler to the patient and 2) “providing a recommendation” to the patient to inhale the composition from the inhaler on an as-needed basis, as determined by the patient based on the patient's symptoms, as a treatment and preventive measure, "when" the patient experiences an increase in asthma symptoms. Further, the term "as needed” described by Applicants encompasses not only the medical "need" determined by the patient but reads on the circumstances where there is **no "need”** of administration of the claimed composition. Therefore, what happens after the patient is recommended to inhale the composition is not an element of the claim. There is **no requirement a practical application** actually be associated with this “recommendation”. “[a] process is … an act, or a series of acts, performed upon the subject matter to be ***transformed*** *and* ***reduced*** to a different state or thing.” In re Schrader, 22 F.3d 290, 293-94, 30 USPQ2d 1455, 1459 (Fed. Cir. 1994), citation omitted. (See also State Street Bank & Trust Co. v. Signature Financial Group Inc., 149 F3d 1368, 1373, 47 USPQ2d 1596, 1601 (Fed. Cir. 1998) holding that a claimed system was statutory subject matter because it produced “a useful, concrete and tangible result.”). In this case, neither a transformation nor reduction would result from the claimed invention because the limitation that the patient actually performs the administration of the claimed composition is not an element of the claim. The "reduction" or "transformation" would **only occur** with the actual administration of the claimed combination. the term "as needed” described by Applicants encompasses not only the medical "need" determined by the patient but reads on the circumstances where there is **no "need”** of administration of the claimed composition. Therefore, in

this case, what happens after the patient is recommended to inhale the composition is not an element of the claim. Thus, no reduction or transformation would take place with the claimed invention because the claims do not recite the necessary step of a practical application associated with the claimed recommendation. That is, a recommendation for action does not guarantee that the required step be taken which would achieve the "reduction" or "transformation" in the process claims.

With regard to 35 U.S.C. 103(a) rejection, Applicants argue that the Examiner acknowledges at page 16 of the Final Office Action that the present claims differ from the disclosure in Carling in that the present claims require recommending that a patient use the inhaler “as needed” as determined by the patient. However, the Examiner asserts that such recommendation would be “obvious”, stating that Carling teaches the dosage “strongly depend on the severity of disease (mild, moderate, severe asthma) and the suitable daily dosages is up to 8 inhalation". In response to this argument, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, it is well known in view of Carling et al. that the combination of formoterol with budesonide has beneficial effect in the treatment of asthma. It is also known that the combination of formoterol and budesonide has not only a greater efficiency and duration of bronchodilator action but

also rapid onset of action. (page 4, lines 3-10). Carling et al. exemplify amounts of each of the active agents (budesonide and formoterol) per dose of inhalation, which calculate up to 8 inhalations per day without going over the maximum daily dosage. Although, Carling recommends twice a day dosing for the treatment of asthma including nocturnal asthma, it does not mean that the changes could not be made to accommodate the patients' medical needs, particularly, when Carling teach that the dosages strongly depend on the severity of the diseases. Therefore, the skilled artisan would have been motivated to instruct the patient to use the Carling et al. composition as needed on the bases of up to 8 inhalation a day for a reasonable expectation of successfully achieving maximum benefit in the treatment of any level of the asthmatic condition. Applicants argue that the budesonide (like other glucocorticoids) was at the time of the invention known to have only an indirect and gradual effect on asthma symptoms, useful for keeping airway inflammation under control as long-term preventative, but considered useless as an emergency bronchodilator. Applicants further argues that Exhibit A shows Symbicort (Trade name for the combination of budesonide and formoterol for the treatment of asthma), its package insert disclose the statement "Do not use Symbicort to relieve an acute attack" and also it should be administered twice a day unless the patient's doctor has decided that administration just once per day is sufficient to control the patient's symptoms.

This is not found to be persuasive because at the time the invention was made, the effective treatment of asthma with the combination of budesonide and formoterol up to 8 inhalations was known in view of Carling et al. It was also known in view of Carling that

the combination of formoterol and budesonide has not only a greater efficiency and duration of bronchodilator action but also rapid onset of action. (page 4, lines 3-10). Therefore, one of ordinary skill in the art would recommend that those patients, currently using the specific Carling et al combination of formoterol and budesonide for maintenance therapy and/or use the combination during an asthmatic attack at a dose up to the limit (up to 8 inhalations per day) recommended by Carling et al for the beneficial effect in the treatment of asthma up to the well known maximum daily dose taught by Carling et al to provide adequate dosage sufficient to treat asthmatic condition.

Thus, the claims fail to patentably distinguish over the state of the art as represented by the cited references.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 13-36, 38, 42 and 43 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 13, 42 and 43 require steps to “providing” a patient as inhaler and “provide” a recommendation to use the inhaler ..”if” or ”when” the patient experiences acute asthma symptoms. It is noted that a process is an act or a series of acts,

performed upon the subject matter to be transformed and reduced to a different state or thing.

Therefore, what happens after the providing steps, the actual administration of the inhaler to patient's body is not an element of the claim. There is no requirement a practical application actually be associated with this provided steps. "[a] process is … an act, or a series of acts, performed upon the subject matter to be *transformed and reduced* to a different state or thing." In re Schrader, 22 F.3d 290, 293-94, 30 USPQ2d 1455, 1459 (Fed. Cir. 1994), citation omitted. (See also State Street Bank & Trust Co. v. Signature Financial Group Inc., 149 F3d 1368, 1373, 47 USPQ2d 1596, 1601 (Fed. Cir. 1998) holding that a claimed system was statutory subject matter because it produced "a useful, concrete and tangible result."). In this case, neither a transformation nor reduction would result from the claimed invention because the limitation that the patient actually performs the administration of the claimed composition is not an element of the claim. The "reduction" or "transformation" would only occur with the actual administration of the claimed combination. Thus, no reduction or transformation would take place with the claimed invention because the claims do not recite the necessary step of a practical application associated with the claimed recommendation. That is, a recommendation for action does not guarantee that the required step be taken which would achieve the claimed "reduction" or "transformation". Therefore, the claimed subject matter is deemed non-statutory.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 13-15, 17, 18, 20-36, 38 and 42-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carling of record.

Carling et al. on page 6, lines 5-30, teach the suitable daily asthmatic dose of formoterol fumarate dihydrate as required by claim 15 and budesonide within Applicant's daily dosage of "on demand" (twice a day) and the dosages strongly depends on the patient (age, weight etc.), severity of disease (mild, moderate, severe asthma etc..).

Carling et al. on pages 7-9 exemplify amounts of active agents per dose of inhalation, which calculate up to 8 inhalation per day without going over the maximum daily dosage.

Carling teaches at page 8-14, page 3, line 35 through page 4, line 10, lines 30-35, page 6, lines 5-30, and page 7, lines 1-5, teach a composition comprising Applicant's active agents use for treating respiratory disorder such as asthma set forth in claims 13-15, 17-18, 20-21, and 23.

Carling et al. at page 4, lines 3-10, also teach that the combination of formoterol and budesonide has not only a greater efficiency and duration of bronchodilator action but also a rapid onset of action.

The difference between Carling et al. and Applicant's invention is recommending a patient to use the inhaler as needed and when needed as determined by the patient based on the patient's symptoms, to provide short-term symptomatic relief of acute asthmatic symptoms set forth in claims 13 and 36, instructing patient to inhale additional doses as needed if he experiences asthma including acute asthmatic episode, a specific carrier set forth in claim 24, the molar ratio of active agents set forth in claim 14, and the particle size set forth in claim 22 and recommendation resulting at least one use of the inhaler set forth in claims 49-53.

However, to recommend the patient to inhale, as needed, as determined by the patient's symptoms in acute asthmatic episode is obvious since Carling et al. teach that the dosages strongly depends on the severity of disease (mild, moderate, severe asthma) and the suitable daily dosage is up to 8 inhalation. One of ordinary skill in the art would be motivated to recommend those patient with severe asthma or acute asthmatic attack to use the Carling's composition as needed bases up to 8 inhalations as suggested by Carling et al. that the dosages strongly depends on the severity of disease and to achieve maximum benefit of daily dosage recommended by Carling et al. It is noted that combination of formoterol with budesonide is well known to be beneficial for the treatment of asthma as taught by Carling et al. Moreover, if that patient experiencing acute asthmatic attack even with ongoing twice a day dosing

regimen, he still can safely inhale additional 6 inhalations without going over the maximum suitable daily dosage in general asthmatic condition taught by Carling et al. to achieve its known therapeutic relief from asthmatic attack. The skilled artisan would have been motivated to recommend that those patients, currently using the specific Carling et al combination of formoterol and budesonide for maintenance therapy, use the combination during an asthmatic attack at a dose up to the limit recommended by Carling et al for such an emergency. One of ordinary skill would recognize that it is advantageous for the patient to self-administer the treatment to avoid the dire consequences of waiting for professional assistance.

Further, patients disclosed by Carlings including those taking twice a day regimen (at least one occasion), e.g. two-times per day to prevent and treat asthma symptoms would be included in the range of "as needed as determined by the patient" because those patients may only “need” twice a day dosing per their medical condition.

The molar ratio of active agents to be used set forth in claim 14, the selection of carrier set forth in claims 23 and 24, and the particle size of active agents set forth in claim 22, are all deemed obvious since they are all within the knowledge of the skilled pharmacologist and represent conventional formulations.

Claim 16 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carling et al. of record as applied to claims 13-15, 17, 18, 20-36, 38, 42-50 above, and further in view of Aberg et al. (U.S.Patent 5,795,564) and Ryrfeldt et al. of record.

Carling et al. as applied as before.

Carling et al. do teach the isomer of formoterol set forth in claim 16 and the specified epimer of budesonide set forth in claim 19.

Aberg et al. teach (R, R) isomer of formoterol as required by claim 16 is a potent bronchodilator with reduced adverse effects in treatment of asthma. (abstract, column, 1, lines 25-35).

Ryrfeldt et al. teach that 22R epimer of budesonide is more potent in the treatment of bronchial asthma than 22S epimer.

However, it would have been obvious to one of ordinary skill in the art to employ (R, R) enantiomer of formoterol and 22 R epimer of budesonide in view of Aberg et al. and Ryrfeldt et al. because both of the references of Aberg and Ryrfeldt teach specific isomers form that possesses potent asthmatic effect of the active agents utilized in Carling reduced adverse effects in treatment of asthma. One would have been motivated to employ (R,R) isomer of formoterol and 22R epimer of budesonide in Carling's composition with reasonable expectation of successfully treating asthmatic patients with reduced adverse effects.

For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited references. The claims are therefore properly rejected under 35 U.S.C. 103.0

None of the claims are allowed.

Communication

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JENNIFER M. KIM whose telephone number is (571)272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JENNIFER M KIM/
Primary Examiner, Art Unit 1617

Jmk
June 11, 2009